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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,682	04/28/2000	DAVID J. FITZGERALD	015280-31010	5396

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	09/462,682		FITZGERALD, DAVID J.	
	Examiner		Art Unit	
	Ginny Portner		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,8,12,13,47-51 and 55-61 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,11 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7-8,12-13,47-51,55-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/27/06</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

Claims 1-3, 7-8, 12-13, 47-51, 55, 56-58 and new claims 59-61 are under consideration.

Claims 4-6, 11, 14-18 stand withdrawn from consideration.

All other claims have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

2. The information disclosure statement filed October 27, 2006 has been considered.

Objections/Rejections Withdrawn

1. Claims 52-54 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been obviated as the claims have been canceled.
2. Claims 55 and 56 objected to because of the following informalities has been obviated by claim amendment.
3. ***Claim Rejections - 35 USC § 112*** Claims 1-3, 7-8, 12-13, 47-55 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been obviated in light of the claims no longer reciting the phrase :“a cell recognition domain of between 10 and 1500 amino acids that binds to an epithelial cell surface receptor on the apical surface of a mucosal membrane of a mammal”.
4. ***Double Patenting*** Claims 1-3 provisionally rejected on the ground of nonstatutory double patenting over claims 1, 11, 17-20, and 42 of copending Application No. 10/432,412 (allowed application), is herein maintained in light of the fact that the copending claims are still pending and an effective terminal disclaimer has not been filed.
5. ***Claim Rejections - 35 USC § 102 Maintained:*** The rejection of claims 1, 7-8, 12, 47-50, 51, 55, and new claim 59 and 61 under 35 U.S.C. 102(e) as being anticipated by Cardy et al (US 2002/0106370, effective filing date May 15, 1995) in light of evidence provided by US Pat. 6,303,120, is herein withdrawn in light of Applicant's traversal.

Art Unit: 1645

Response to Arguments

6. Applicant's arguments filed October 27, 2006 have been fully considered but they are not persuasive.

7. ***Rejections Maintained*** : The rejection of amended claims 1-3, 7-8, 12-13, 47-50, 51-58 as previously applied to claims 1 and 47, under 35 USC 112, first paragraph written description is traversed on the grounds that the examiner is reading the claim more broadly than intended.

8. It is the position of the examiner that the invention claimed need only comprise an amino acid sequence of 280-344 that shares 95% (98% identity, claim 47) identity to this sequence and evidences translocation activity, while Example 14 requires that variants to be 95 % identical to the entire SEQ ID NO and does not recite the term "homolog" as asserted by Applicant.

9. This rejection could be obviated by amending the claim to recite -----a translocation domain comprising the translocation domain of Pseudomonas exotoxin A (PE), wherein the translocation domain is 95% identical to SEQ ID NO 2 from amino acid position 280 to amino acid position 344 and serves to translocate the instant chimeric immunogen to the cytosol of a cell----- . The examiner's responses to traversal from the action dated April 1, 2006 are incorporated herein by reference

New Grounds of Rejection

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 7-8, 12, 47-50, 51, 55, and new claim 59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardy et al (WO95/31483, reference provided by Applicant in US PTO 1449) in light of Donnelly et al 1993, PNAS (reference incorporated by reference in Cardy et al, page 5, second half of paragraph).

Art Unit: 1645

Cardy et al disclose the instantly claimed invention that comprises

- a) a cell binding domain(see Figure 10, pages 8-9, page 8, paragraphs 7-8 and page 9, paragraph 1 (antibody binding cell recognition receptor and claim 10, page 20)
- b) a translocation domain of Pseudomonas exotoxin translocation domain (see page 5, lines 15-20, in light of Donnelly et al 1993 that describes the sequence of the translocation domain);
- c) an epitope (see “vaccines through the inclusion of adjacent immunodominant B and T-cell epitopes”, see page 6, paragraph 1, lines 7-8), wherein the epitope is the “HIV V3-loop epitope (see page 15, Example 7 and claim 11, page 11); and
- d) a endoplasmic reticulum retention domain (see Figure 10 “KDEL”, and page 8, figure 10 narrative and last paragraph of page 8).

By all comparable data, the disclosure of Cardy et al describes the same or equivalent chimeric immunogen as now claimed. Cardy et al anticipates the instantly claimed invention as now claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
January 8, 2007



MARK NAVARRO
PRIMARY EXAMINER